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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/593,089

09/10/2007

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47038-0247-00 (227744)

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55694 7590 05/25/2010
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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1656

NOTIFICATION DATE

DELIVERY MODE

05/25/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBRIPIDocket@dbr.com
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|------------------------------|---------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/593,089 | Applicant(s) ALLEN ET AL. | |
| | Examiner MARYAM MONSHIPOURI | Art Unit 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-21 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 is/are allowed.
- 6) ☒ Claim(s) 2-8, 10-21, 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1, 22-32 are canceled. Claims 2-21, and 33-36 are still at issue and are present for examination.

Applicants' arguments filed on 2/24/2010 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

On 5/14/2009 the examiner called up the attorney of applicant (Mr. Brian K. Lathrop) to negotiate allowance. However, said negotiation did not result in any agreements.

Information Disclosure Statement

Applicant inquired about some World patent documents which were not initialed in the IDS of 9/2006. Applicant is welcome to review the prior art references of record filed 9/15/2009. As applicant can observe for himself/herself no World patent document appear to have been filed on said date.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-8, 10-21, 33-36 remain rejected under 35 U.S.C. 103(a) as being unpatentable over McCarthy (cited previously) in view of current large scale recombinant [protein isolation and purification method, according to previous office

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action. In traversal of this rejection applicant argues the following: **(1)** McCarthy's process of producing Dkk proteins does not provide a concentration step and the Office produces no evidence that it would have been obvious to include one. Further, even if the Office could provide relevant evidence suggesting a concentration step, McCarthy's process of producing Dkk proteins does not involve using a detergent and EDTA. McCarthy suggests using a detergent for the separate purpose of solubilizing Dkk in cell free assays. The Office provides no reason why solubilizing Dkk in cell free assays would have suggested the use of detergent during concentration of Dkk. Therefore in view of applicant this rejection must be withdrawn.

(2) The present disclosure provides secondary evidence that must be weighed in a consideration of obviousness. Specifically the specification (pages 17, lines 22-34) teaches that the combination of EDTA and a detergent synergistically increases the overall yield of Dkk 5 fold, compared to the yield obtained with either alone. Therefore, the claims are non-obvious, even if the Office *arguendo* established *prima facie* obviousness.

These arguments were fully considered but were **unpersuasive**. In response to applicant's **first** argument it should be noted that the examiner agrees with applicant that McCarthy does not explicitly teach a concentration step and it is for said reason that said art was not cited as 102 rejection. Applicant is requested to review columns 81-82 of McCarthy again wherein large amounts of hDkk-3flag.long protein in a total volume of 11.0 ml was loaded and bound to an anti-Flag M2 affinity column and wherein after

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elution and dialysis most of said protein had been collected in a total volume of 4 ml. Surely reducing the volume from 11.0 ml to 4.0 ml inherently involves concentration.

Regarding the non-obviousness of utilizing detergent and EDTA in hDkk3 concentration process it should be noted that, as mentioned previously, detergents such as Tween and Triton and metal chelators such as EDTA are commonly known to be necessary for maintaining protein solubilization and activity and are routinely added to cell lysates. Such cell lysates are subsequently added to affinity columns without detergent or EDTA removal. Applicant is reminded that he/she in base claim 33 does not specify any EDTA or detergent concentrations. Therefore, to one of ordinary skill with a reasonable expectation of success, such ingredients (i.e. EDTA and Tween) would inherently be present in any cell lysate including that of McCarthy's (even if the reasons for their incorporation into cell lysate may be different than those of instant invention) before and during protein isolation and purification.

With respect to applicant's **second** argument it may be true that the combination of specific concentrations of Tween-20 and EDTA results in surprisingly high yields of hDkk proteins. However, base claim 33 (and its dependent claims 2-8, 10-21 and 34-36) neither mentions Tween-20 nor , as mentioned above, specifies the concentrations of EDTA and Tween-20 utilized to obtain said surprisingly high overall yields of protein recovery. Therefore the examiner finds no reason to withdraw the rejection.

Note:

Claim 9 is allowed. This is because a method of concentrating an active, glycosylated Dkk protein comprising concentrating a culture media containing said

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protein in the presence of 0.01% to about 1% Tween-20 and EDTA in the amount of 0.01 mM to about 2 mM is free of prior art. Further, the prior art fails to suggest such specifically claimed method. Hence, said method is also non-obvious.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MARYAM MONSHIPOURI** whose telephone number is (571)272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m. to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rao Munjunath can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656
